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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,603	12/22/1999	DAVE BOVA	20720-103793	6359

7590 06/04/2003

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	**PAPER NUMBER**
1615	12

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,603	BOVA, DAVE	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Response filed on November 18, 2002. Receipt is also acknowledged of applicant's Petition to Revive and the granting of that petition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No.

6,080,428. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,080,428 claims a method of treating hyperlipidemia by administering an effective amount of nicotinic acid once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage.

The instant claims recite a method of treating hyperlipidemia by administering an effective amount of nicotinic acid or *a compound metabolized to nicotinic acid by the body* once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage. The difference in the instant claims being the inclusion of compounds that are metabolized to nicotinic acid by the body. U.S. Patent No. 6,080,428 further defines the terms "nicotinic acid" to include specific compounds that are metabolized to nicotinic acid by the body (Col. 3, lines 30-41). Therefore, the claims of U.S. Patent No. 6,080,428 include all of the compounds recited in the Specification that can be metabolized to nicotinic acid by the body.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to treat hyperlipidemia with nicotinic acid or a compound that metabolizes to nicotinic acid in the body.

One of ordinary skill in the art would have been motivated to do this to achieve the same desired results with various compounds based on availability, price or efficacy of the individual compounds.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 34-132 of U.S. Patent No. 6,129,930. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,129,930 claims a method of treating hyperlipidemia by administering an effective amount of nicotinic acid once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage.

The instant claims recite a method of treating hyperlipidemia by administering an effective amount of nicotinic acid or *a compound metabolized to nicotinic acid by the body* once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage. The difference in the instant claims being the inclusion of compounds that are metabolized to nicotinic acid by the body. U.S. Patent No. 6,129,930 further defines the terms "nicotinic acid" to include specific compounds that are metabolized to nicotinic acid by the body (Col. 3, lines 49-57). Therefore, the claims of U.S. Patent No. 6,129,930 include all of the compounds recited in the Specification that can be metabolized to nicotinic acid by the body.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to treat hyperlipidemia with nicotinic acid or a compound that metabolizes to nicotinic acid in the body.

One of ordinary skill in the art would have been motivated to do this to achieve the same desired results with various compounds based on availability, price or efficacy of the individual compounds.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

Response to Arguments

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Due to the new grounds of rejection, this action is deemed non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
May 29, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600